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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/599,692	10/05/2006	Prediman K. Shah	67789-623	2885

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EXAMINER	
EPPS -SMITH, JANET L	

ART UNIT	PAPER NUMBER
1633	

MAIL DATE	DELIVERY MODE
08/06/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/599,692	SHAH ET AL.	
	Examiner	Art Unit	
	Janet L. Epps-Smith	1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 April 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-35* is/are pending in the application.

4a) Of the above claim(s) *1-16 and 29-35* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *17-28* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *4-27-07; 10-05-06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election of Group IV claims 17-28 in the reply filed on 04/10/209 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

2. Claims 1-16 and 29-35 are now withdrawn as being directed to a non-elected invention.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. Claims 17-28 are rejected under 35 U.S.C. 103(a) as being obvious over Fan et al. in view of Oka et al. and Sharif et al.

5. Instant claims 17-18 are drawn to the following:

17. A method of treating a condition in a mammal, comprising: providing a recombinant adeno-associated viral (rAAV) vector comprising an exogenous gene encoding Apolipoprotein A-I (ApoA-I), ApoA-I Milano, a fragment of ApoA-I or ApoA-I Milano, or a derivative of ApoA-I or ApoA-I Milano; and delivering said rAAV vector to said mammal in an amount sufficient to treat said condition.

18. The method of claim 17, wherein said exogenous gene is ApoA-I Milano.

Fan et al. teach the AAV-based delivery of human apolipoprotein A-I into the skeletal muscle for the treatment of atherosclerosis. Page 1435 of this reference describes the construction of the AAV-based plasmid vectors, the vectors where designed to comprise the 5' and 3' ITRs of AAV-2, see the following schematic representation of the vectors used in this reference:

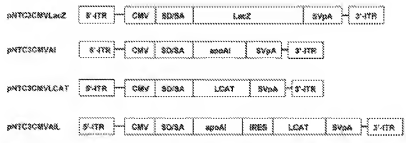

Figure 1 Schematic representation of AAV-based plasmid expression vectors. The various expression cassettes are indicated and were synthesized as described in the Materials and methods section. ITR, inverted terminal repeat of AAV; CMV, cytomegalovirus IE promoter/enhancer; SD/SA, SV40 intron; pA, SV40 virus polyadenylation signal; LacZ, E. coli β-galactosidase coding region; apoAI, human apoAI cDNA; LCAT, human LCAT cDNA. The plasmid backbone is not included and the diagrams are not to scale.

However, Fan et al. does not teach wherein the Apo A-I gene is the Apo A-I Milano gene, or wherein the administration comprises delivery to bone marrow cells.

Oka et al. teach the administration of AAV particles expressing Apo A-I Milano gene for the treatment of atherosclerosis. Oka et al. teaches that Apo A-I Milano was demonstrated to have even stronger anti-atherogenic effects than wild type ApoA-I. Additionally, Oka et al. teach the transduction of rAAV expressing Apo A-I Milano into bone marrow cells of ApoE-deficient mice, and the intramuscular injection of rAAV into another group. 20 weeks after treatment the mice were then analyzed for atherosclerosis. The authors found 60-70% reduction in lesion area in mice that received bone marrow expressing Apo A-I Milano, and 38-4% reduction in mice that received intramuscular injection.

Sharif et al. teach adeno-associated virus mediated Apo A-I Milano gene therapy for the treatment of atherosclerosis and restenosis. Sharif et al. provided preliminary data using in vivo studies demonstrating successful gene transcription in vivo. In order to increase production of Apo A-I Milano, the AAV vector was optimized.

It would have been obvious to the ordinary skilled artisan to modify the teachings of Fan et al., Oka et al. and Sharif et al. in the design of the claimed invention. First, one of ordinary skill in the art would have been motivated to modify the teachings of Fan et al. with the teachings of Oka et al. and Sharif et al. since Oka et al. in particular, teach that Apo-A-I Milano was demonstrated to have a greater anti-atherogenic effect than that observed for wild-type Apo A-I.

In regards to the various limitations recited in claim 23 regarding the amount of vector administered to a mammal, since the general conditions of the claimed invention are disclosed in the prior art, absent evidence to the contrary, as per MPEP § 2144.05 [R-5], "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955).

Moreover, regarding the rationale for combining prior art elements according to known methods to yield predictable results, all of the claimed elements were known in the prior art and one skilled in the art could have combined the element as claimed by known methods with no change in their respective functions, and the combination would have yielded predictable results to one of ordinary skill in the art at the time of the invention.

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Janet L. Epps-Smith whose telephone number is 571-272-0757. The examiner can normally be reached on M-F, 10:00 AM through 6:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Woitach can be reached on 571-272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Janet L. Epps-Smith/
Primary Examiner, Art Unit 1633